IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

LESA LAKE-ALLEN, individually and in her capacity as Personal Representative of the Estate of SCOTT ALLEN and his heirs-at-law, and as the parent and guardian of minors KML, SAL-A and SAL-A,

Plaintiff,

vs.

JOHNSON & JOHNSON, L.P. a/k/a JANSSEN PHARMACEUTICA PRODUCTS, L.P., and ALZA CORPORATION,

Defendant.

MEMORANDUM DECISION AND ORDER

Case No. 2:08CV00930DAK

This matter is before the court on Defendants' Motion to Dismiss the causes of actions in Plaintiffs' Complaint that state claims for design defect liability, as well as the cause of action for punitive damages. The court held a hearing on these motions on June 25, 2009. At the hearing Plaintiffs were represented by Michael D. Lurie and Defendants were represented by Lauren A. Shurman and John A. Anderson. Before the hearing, the court carefully considered the memoranda and other materials submitted by the parties. Since taking the motion under advisement, the court has further considered the law and facts relating to the motion. Now being fully advised, the court renders the following Memorandum Decision and Order.

BACKGROUND

Plaintiff Lesa Lake-Allen is an individual residing in Taylorsville, Utah. Ms. Lake-Allen is the widow of Scott Allen and personal representative of the heirs-at-law of the estate of Mr. Allen and the parent and guardian of his children. Ms. Lake-Allen alleges that Scott Allen died as a result of his use of Duragesic®, a prescription pain patch that delivers fentanyl. Duragesic® is an FDA-approved prescription transdermal pain medication containing fentanyl, an opioid analgesic.

J&J is a corporation based out of New Jersey, and has a substantial presence worldwide in the consumer, pharmaceutical, and medical device and diagnostics markets. Alza is a Delaware corporation with its primary office located in California. Alza and Janssen are responsible for manufacturing, marketing, selling, distributing and promoting the Duragesic® patch in Utah and other locations nationally. Alza is a subsidiary of J&J, which is the sole shareholder and is responsible for Alza's commercial operations. Janssen is a New Jersey limited partnership, with its principal office located in New Jersey. Janssen Pharmaceutica, Inc. is the general partner of Janssen, a wholly owned subsidiary of J&J, and a Pennsylvania corporation with its principal place of business in New Jersey.

Plaintiffs allege that Defendants played various roles in the design, manufacture, and marketing of Duragesic®, which was allegedly involved in Mr. Allen's death. Plaintiffs contend that Mr. Allen's death was due to a deadly dose of fentanyl introduced into his body via the reservoir system of a Duragesic® patch. Plaintiffs contend that Defendants had a safer design, the "matrix" design, which was being marketed in Europe at the time of Mr. Allen's death. In December 2008, Plaintiffs filed a Complaint containing six causes of action: negligence, strict liability, breach of implied warranty, breach of express warranty, wrongful death, and punitive

damages. On March 23, 2009, Defendants filed this motion to dismiss all causes of action that are based on design defect liability, as well as the cause of action for punitive damages.

DISCUSSION

A. Choice of Law

Defendants claim that Utah law governs all claims and, as such, Defendants' motion is based upon Utah law. Plaintiffs, however, contend that the current record is insufficient to decide the choice of law, and further argue that, even if the record were sufficient, California or New Jersey law would be more appropriate because the products were designed and manufactured in those states. Due to the differences in the law in these states, it is necessary to decide these issues before the motion can be considered.

Utah applies the Restatement's "most significant relationship" approach to resolving the choice of law issue in tort cases. *Waddoups v. Amalgamated Sugar Co.*, 54 P.3d 1054, 1060 (Utah 2002). This analysis involves the consideration of four factors, which are to be "evaluated according to their relative importance with respect to the particular issue." *Id.* (citing Restatement (Second) Conflict of Laws § 145(2) (1971)). The four factors include the following:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parities, and
>
> (d) the place where the relationship, if any, between the parties is centered.

In the case at bar, the injury occurred in Utah. However, the conduct allegedly causing the injury most likely occurred in New Jersey or California, where the product was designed and manufactured. Plaintiffs are Utah residents, while Defendants are incorporated and have their

principle places of business in New Jersey, California, and Pennsylvania. Mr. Allen purchased and used the Duragesic® patch in Utah, where he also suffered the injury that allegedly caused his death. As such, the court finds that Utah bears the most significant relationship to the claims at issue.

As in *Grange v. Mylan Laboratories, Inc.,* No. 1:07-CV-107, 2008 WL 4813311 (D. Utah Oct. 31, 2008), the fact that the Duragesic® patch was designed and manufactured in other states does not overcome the strength of the contacts in Utah, where the drug was marketed, sold, prescribed, taken, and allegedly injured Mr. Allen. The *Grange* court also relied on (or recognized) the finding of another prescription drug case of the federal court for the Eastern District of Pennsylvania stating that "[m]ost if not all contacts with the class members, such as marketing, prescribing and taking the drug, were in the home states . . . . Thus, the state[] having the most significant contacts and relationship to the liability issue is [the plaintiff's] home state." *Id*. (quoting *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 194 (E.D. Pa. 2007)).

Accordingly, Utah has the most significant contacts to the issues alleged in this case and the court will apply Utah law to each claim.

B. Motion to Dismiss Design Defect Claims

Defendants move to dismiss all causes of action that are based upon the theory of design defect liability, which include Plaintiffs' strict liability and negligence claims. Defendants argue that all prescription drugs approved for use by the United States Food and Drug Administration ("FDA") are "unavoidably unsafe" and, as such, there can be no strict liability claim for a design defect in these products. *Grundberg v. Upjohn*, 813 P.2d 89 (Utah 1991).

Defendants further argue that this holding should be extended beyond strict liability to bar all design defect claims (i.e. negligence claims) for prescription drugs because the *Grundberg*

court stated that "FDA-approved prescription drugs cannot be defective in design" and because the policy reasons given in *Grange* are applicable to all design defect claims. Plaintiffs, however, contend that the Duragesic® patch is more akin to a drug container and is therefore not exempt from any design defect claims.

Plaintiffs' argument that the patch is more akin to a container is unpersuasive. The Duragesic® patch was approved by the FDA as a drug and to categorize it as a container is akin to categorizing any substance available in a time release capsule as a container. In the case of prescription pharmaceutical patches, it is nonsensical to separate the liability of the overall product and the substance that it releases. As such, *Grundberg* applies and Plaintiffs' strict liability claim is dismissed to the extent that it is based on a theory of design defect.

The court does not agree, however, with Defendants' contention that the bar on design defect claims should be extended beyond strict liability. When the *Grundberg* court adopted Comment K of Section 402A of the Restatement (Second) of Torts (1965), it clearly noted that the purpose "is to protect from *strict liability* products that cannot be designed more safely." *Id.* at 93 (emphasis added). Since *Grundberg*, Utah courts have consistently limited the application of this exemption to strict liability claims. Moreover, the policy reasons discussed in *Grange* specifically pertained to strict liability claims and must be considered in this context. Thus, this court finds that the exemption on design defect liability for prescription drugs is properly limited to strict liability, and to the extent Defendants' motion seeks dismissal of non-strict-liability claims based upon design defect, their motion is denied.

C. Motion to Dismiss Punitive Damages Claim

Defendants move to dismiss the cause of action for punitive damages, arguing that under Utah Code Annotated §78B-8-203(1), to state a claim for punitive damages against a

manufacturer of a prescription drug approved by the FDA, there must be proof of fraud upon the FDA. Defendants further contend that the United States Supreme Court has ruled that fraud upon the FDA claims are preempted by federal law, meaning that the FDA must first find that it has been defrauded by the sponsor of a medication. *Buckman Co. v. Plaintiff's Legal Comm'm.*, 531 U.S. 341, 348 (2000). Defendants correctly note that another judge in this court recently relied on *Buckman* to dismiss a punitive damages claim against another manufacturer of a fentanyl medication because the plaintiffs did not plead that the FDA had found that it had been defrauded. *Grange*, 2008 WL 4813311 at 7. Because Plaintiffs have not alleged that the FDA has determined that it was defrauded, Defendants argue that the cause of action for punitive damages should be dismissed.

On the other hand, Plaintiffs argue that the more recent Supreme Court decision *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) clarifies the "presumption against preemption" standard and, under this standard, federal law does not preempt Utah Code Annotated §78B-8-203(1). In *Wyeth*, the Court explained the rigidity of the presumption against preemption, noting that federal preemption requires a "clear and manifest purpose of Congress." 129 S. Ct. 1187 (2009) (quoting *Meditronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Specifically, in regard to the FDA, the Court also recognized that "Congress took care to preserve state law" and that "when Congress enacted an express preemption provision for medical devices . . . it declined to enact such a provision for prescription drugs." 129 S. Ct. at 1196.

In contrast to the case at bar, *Buckman* was a "fraud-on-the-agency" case regarding a medical device, and the state law in that case was preempted by the Medical Device Amendments of 1976. 121 S. Ct. 1012, 1014 (2001). Accordingly, the federal preemption articulated in *Buckman* extends only to medical devices and not to prescription drugs.

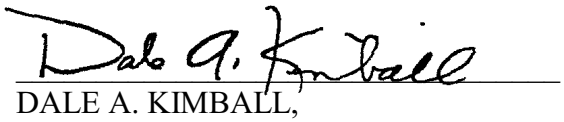
Defendants have not offered any authority suggesting that Congress intended to preempt Utah Code Annotated §78B-8-203(1) in regard to prescription drugs or that the state and federal laws are entirely incompatible. Accordingly, their request to dismiss the punitive damages claim is denied.

CONCLUSION

Defendants' Motion to Dismiss is GRANTED in part and DENIED in part. Plaintiffs' strict liability cause of action is DISMISSED to the extent that it is based upon a design defect claim. However, Defendants' request to dismiss all other claims based upon design defect is DENIED, and Defendants' request to dismiss the claim for punitive damages is also DENIED.

DATED this 27th day of July, 2009.

BY THE COURT:



DALE A. KIMBALL,
United States District Judge